PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P213580PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/NL2005/000269	International filing date *(day/month/year)* 08.04.2005	Priority date *(day/month/year)* 09.04.2004

International Patent Classification (IPC) or national classification and IPC
INV. A23L1/29

Applicant
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1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09.02.2006	04.07.2006

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/NL2005/000269

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets whic have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-9 as originally filed

   Claims, Numbers

   1-18 received on 10.02.2006 with letter of 09.02.2006

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☒ the claims, Nos. 1-16
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

   * *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 17,18

because:

☒ the said international application, or the said claims Nos. 17,18 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*.

☐ no international search report has been established for the said claims Nos.

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☐ neither restricted the claims nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according t Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13. is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industria applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,2,4
	No:	Claims	3,5-16
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-16
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations (Rule 70.7):

   see separate sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/NL2005/000269

1. The amendments filed with the letter dated 09.02.2006 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:
claim 1: "a protein fraction in an amount of 8.2-12 g per 100 ml" and "and the protein fraction comprises at least 8.2 g of intact protein per 100 ml", which was stated to be based on p.3 l.33; however, the disclosure on p.3 l.33 reads: "intact protein 7.8-12 or 8.2-11 g per 100 ml product" (underlining added).

Regarding claims 17 and 18 filed with the letter dated 09.02.2006, the treatment of different requests is not foreseen under the PCT.

Therefore, the IPER is based on the claims as originally filed:

2. Reference is made to the following documents:

D1: WO 2004/026294 A (NOVARTIS NUTRITION AG ; TROUP JOHN P (CH); WOLFE ROBERT R (US)) 1 April 2004 (2004-04-01)

D2: DATABASE WPI Section Ch, Week 200327 Derwent Publications Ltd., London, GB; Class A92, AN 1996-405976 XP002294223 & JP 03 393946 B2 (TERUMO CORP) 7 April 2003 (2003-04-07)

D3: US-B-6 200 9501 (MICHALSKI TOM ET AL) 13 March 2001 (2001-03-13)

D4: EP-A-0 747 395 (CLINTEC NUTRITION CO) 11 December 1996 (1996-12-11)

D5: US-A-5 683 984 (JOST ROLF) 4 November 1997 (1997-11-04)

D6: US-B-6 423 3541 (MONTE WOODROW C) 23 July 2002 (2002-07-23)

2. The common concept linking together the independent claims 1, 3, 5 and 15 is the following:
"A liquid food product having an energy density of at least 1.45 kcal/ml and comprising protein, carbohydrates and fats."
This common concept is not novel, see D1-D4. Thus, the application lacks unity within the meaning of Rules 13.1 and 13.2 PCT.

Independent claims 1, 3, 5 and 15 comprise different technical features, e.g. the feature "a protein fraction in an amount of 7.8-12 g per 100 ml, characterised in that at least 70 wt.% of the protein fraction is obtained by demineralising milk", part of claims 1 and 5, is lacking

in claims 3 and 15. As this nor any corresponding technical feature is present in claims 3 and 15, the technical relationship between the subject-matter of claims 1, 3, 5 and 15 required by Rule13.2 is lacking, and the requirement for unity of invention referred to in Rule 13.1 PCT is not fulfilled.

Furthermore, Article 6 PCT is not met, because claims 1, 3, 5 and 15 have been drafted as separate independent claims and therefore lack conciseness.

3. D1 discloses (see p.7 l.4-p.8 l.9) a nutritional formula (complete) for controlling cachexia, having a caloric density of about 1.5 kcal/ml and containing protein (intact protein and amino acids), carbohydrate and fat. The intact protein may be chosen from e.g. casein, whey protein (see p.3 l.1-2, p.6 l.6-9). A suitable serving size may be in the range of 20 to 500 ml (p.11 l.14-28). The products disclosed in Examples 5 and 6 contain fractions falling in the ranges claimed in present claims 3, 5 and 15. The protein Ca Caseinate (see Examples 5A, 5B and 6) may be obtained by demineralising milk. In Examples 5A and B, the amount of intact protein is about 7.3 and of amino acids 1.9 g per 100 ml. In Example 6 the amount of intact protein is about 7.9 g per 100 ml and of amino acids 2 g per 100 ml.
D2 discloses a liquid food, having an energy value of more than 1.5 kcal/ml and containing whole milk protein, hydrocarbon (in Example 26.25 g dextrin per 100 ml) and fat. The concentration of total protein is 4.2-8.8 g/100 ml.
D3 discloses (see col.3 l.46-col.4 l.5, col.6 l.55-col.7 l.45) a nutritional product, having a caloric density of 1.4 to 1.8 kcal/ml, a carbohydrate (maltodextrin, corn starch, sucrose) content of 19 g/100 ml, a protein content of 6 g/100 ml (hydrolysed whey protein, less than 2% free amino acids) and fat 5.9 g /100 ml.
D4 discloses (claims 1-10, p.4 l.38-40, p.5 l.45-p.6 l.39) an enteral composition, having a caloric density of 1.6-2.25 kcal/ml, 3-4 g/100 ml protein, 23-32 g/100 ml carbohydrate (maltodextrin, hydrolysed corn starch) and 6.6-9 g/100 ml fat. The composition is free of electrolytes (p.5 l.16-18) and 50% of the protein is whey protein (claim 10).
D5 teaches (see col.1 l.1-62) that Ca caseinates are suitable for enteral compositions but cause a foreign taste, whereas the use of skimmed milk powder as a casein source is unsuitable, because it contains too much lactose and Na/K caseinate has a high viscosity. The enteral compositions of D5 contain native micellar casein, obtained by microfiltration of skimmed milk. In Example 2 an enteral composition with an energy density of 1.5

kcal/ml is disclosed, containing 8% (p/v) protein, 16% carbohydrates (maltodextrin, sucrose), 6% fat and having a low viscosity.
D6 discloses (col.3 l.60-67) a low pH, high nutritional food composition, utilising casein or milk protein isolates comprised mostly of casein as the sole or majority protein source with high antimicrobial activity and long shelf life. The caloric content is in the range of 0.5 to 2 kcal/ml (col.8 l.11-15). In Examples 4-6, food compositions are disclosed, providing 2 kcal/ml, containing 6.27-6.96 wt.% milk protein isolate, about 20 wt.% carbohydrate (maltodextrin, sucrose) and 8-9 wt.% lipid.

The subject-matter of the independent claims 3, 5 and 15 is anticipated (Articles 33(2) PCT) by D1-D6.
The subject-matter of dependent claims 4, 6-14 and 16 is not considered to involve an inventive step (Article 33(3) PCT) in view of the same documents, because there seems to be no surprising effect present.

The subject-matter of claims 1 and 2 was not disclosed in any of the cited documents. However, it does not appear to contain inventive subject-matter:
D1 is considered to be the closest prior art and differs in the nature of the protein, which is presently "70 wt.% obtained by demineralising milk and comprising 25-37 wt.% whey proteins". As D5 points to the use of demineralised protein fraction, for the reason of having low viscosity and better taste (see col.1 l.14-62), the combined teachings of D1 with D5 would lead to the present subject-matter.

Claims (45)

1. A liquid complete nutritional composition suitable for feeding cachectic patients, having an energy density of at least 1.45 kcal/ml (at least 6.06 kJ/ml), comprising:
- a carbohydrate fraction in an amount of 17-27 g per 100 ml (0.68-1.08 kcal/ml);
- a protein fraction in an amount of ~~7.8~~ 8.2-12 g per 100 ml (0.31-0.48 kcal/ml); and
- a lipid fraction;
characterised in that at least 70 wt.% of the protein fraction is obtained by demineralising milk, and the protein fraction comprises between 25 and 37 wt.% of whey proteins, and the protein fraction comprises at least 8.2 g of intact protein per 100 ml.

2. A liquid composition according to claim 1, in which said demineralising is achieved by ultrafiltration.

3. A liquid composition according to claim 1 or 2, *characterised* in that the carbohydrate fraction comprises 15-45 wt.% of non-reducing mono-, di- and/or trisaccharides other than sucrose.

4. The composition according to claim 3, wherein the non-reducing disaccharides comprise trehalose.

5. A liquid complete nutritional composition suitable for feeding cachectic patients, having an energy density of at least 1.45 kcal/ml (at least 6.06 kJ/ml), comprising:
- a carbohydrate fraction in an amount of 17-27 g per 100 ml (0.68-1.08 kcal/ml);
- a protein fraction in an amount of ~~7.8~~ 8.2-12 g per 100 ml (0.31-0.48 kcal/ml); and
- a lipid fraction;
characterised in that at least 70 wt.% of the protein fraction is obtained by demineralising milk, and the protein fraction comprises less than 5 wt.% of free amino acids, and the protein fraction comprises at least 8.2 g of intact protein per 100 ml.

6. A liquid composition according to any one of claims 1-5, in which the protein fraction comprises at least 1.0 wt.% of cysteine residues.

7. A liquid composition according to any one of claims 1-6, which comprises 0.5-6 g fibre per 100 ml.

8. A liquid composition according to any one of claims 1-7, wherein the protein fraction amounts to at least 8.5, preferably above 8.7 g per 100 ml.

9. A liquid composition according to any one of claims 1-8, in which the protein fraction contains at least 8.6 wt.% of lysine residues, at least 2.5 wt.% of methionine residues and at least 0.5 wt.% of cysteine residues.

10. The composition according to any one of claims 1-9, wherein the protein fraction essentially consists of intact proteins and comprises 60-90 wt.%, preferably 65-78 wt.% of caseins.

11. The composition according to any one of claims 1-10, wherein the lipid fraction amounts to 5.0-7.0 g per 100 ml (0.45-0.63 kcal/ml).

12. The composition according to any one of claims 1-11, having a viscosity of the liquid of below 50 mPa.s at a shear rate of 100 s^{-1} and a temperature of 20°C.

13. A liquid composition according to any one of claims 1-12, wherein the amount of digestible carbohydrates is 18-23.5 and preferably 18-22 g per 100 ml.

14. A packaged food product containing between 5 and 250 ml of the composition according to any of claims 1-13 in a unit package.

15. A powder that after reconstitution with water provides a composition according to any one of claims 1-13.

16. A process for preparing a liquid product according to any one of claims 1-13, comprising preparing a liquid protein fraction and subsequently mixing with a carbohydrate fraction and a fat fraction, characterised by dissolving in an aqueous solution a dry demineralised milk product, optionally together with a part of other water-soluble components, adjusting the suspension obtained to a viscosity value of below 50 mPa.s (at 100 s^{-1}) and then mixing an amount of this suspension with water or remaining ingredient, including the fat fraction, to arrive at the final composition.

17. A liquid complete nutritional composition suitable for feeding cachectic patients. having an energy density of at least 1.45 kcal/ml (at least 6.06 kJ/ml), comprising:
- a carbohydrate fraction in an amount of 17-27 g per 100 ml (0.68-1.0 kcal/ml);
- a protein fraction; and
- a lipid fraction;
characterised in that:
- the carbohydrate fraction comprises
  = 0-35 wt.% of sucrose;
  = 15-45 wt.% of other non-reducing mono-, di- and/or trisaccharides:
  = 5-50 wt.% of other mono- and disaccharides:
  = 5-40 wt.% of other trisaccharides and higher saccharides.

18. A packaged food product containing between 5 and 150 ml of a liquid food product having an energy density of at least 1.45 kcal/ml and comprising at least 7.6 g protein per 100 ml and comprising carbohydrates and fats and optionally vitamins, in a unit package.